

Translation

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 0000054756	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. PCT/EP2004/007957	International filing date (day/month/year) 16.07.2004	Priority date (day/month/year) 01.08.2003
International Patent Classification (IPC) or national classification and IPC C11B1/02, C12N9/02, C12N9/10, A01K67/027		
Applicant BASF PLANT SCIENCE GMBH		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 11 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> (sent to the applicant and to the International Bureau) a total of _____ sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input checked="" type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/EP	Authorized officer
Facsimile No.	Telephone No.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/007957

Box No. I

Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____ which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1-140 _____ as originally filed/furnished
- pages* _____ received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. 1-34 _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* _____ received by this Authority on _____
- nos.* _____ received by this Authority on _____
- ☒ the drawings:
- sheets 1/30-30/30 _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☒ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/007957

Box No. III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 12-34

because:

☐ the said international application, or the said claims Nos. _____
relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 12-34

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished☐ does not comply with the standard

the computer readable form

☐ has not been furnished☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See Supplemental Box for further details.

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/007957

Box No. IV

Lack of unity of invention

1. ☒ In response to the invitation to restrict or pay additional fees the applicant has:
- ☐ restricted the claims.
 - ☐ paid additional fees.
 - ☐ paid additional fees under protest.
 - ☒ neither restricted the claims nor paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is:
- ☐ complied with.
 - ☒ not complied with for the following reasons:

See supplemental sheet.

4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
 - ☒ the parts relating to claims Nos. 1-11

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/007957

Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	<u>1-11</u>	YES
	Claims		NO
Inventive step (IS)	Claims		YES
	Claims	<u>1-11</u>	NO
Industrial applicability (IA)	Claims	<u>1-11</u>	YES
	Claims		NO
2. Citations and explanations (Rule 70.7)			
This report makes reference to the following documents:			
D1:	DREXLER H ET AL: "Metabolic engineering of fatty acids for breeding of new oilseed crops: Strategies, problems and first results" JOURNAL OF PLANT PHYSIOLOGY, FISCHER, STUTTGART, DE, vol. 160, no. 7, July 2003 (2003-07), pages 779-802, XP002266491 ISSN: 0176-1617		
D2:	BEAUDOIN FREDERIC ET AL: "Heterologous reconstitution in yeast of the polyunsaturated fatty acid biosynthetic pathway" PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF USA, NATIONAL ACADEMY OF SCIENCE. WASHINGTON, US, vol. 97, no. 12, 6 June 2000 (2000-06-06), pages 6421-6426, XP002200201 ISSN: 0027-8424		
D3:	DOMERGUE F ET AL: "Cloning and functional characterization of Phaeodactylum tricornutum front-end desaturases involved in eicosapentaenoic acid biosynthesis" EUROPEAN JOURNAL OF BIOCHEMISTRY, BERLIN, DE, vol. 269, no. 16, August 2002 (2002-08), pages 4105-4113, XP002228745 ISSN: 0014-2956		
D4:	ZANK T K ET AL: "Cloning and functional expression of the first plant fatty acid elongase specific		

Box No. V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

for DELTA6-polyunsaturated fatty acids"

BIOCHEMICAL SOCIETY TRANSACTIONS, COLCHESTER,
ESSEX, GB, vol. 28, no. 6, December 2000 (2000-
12), pages 654-658, XP002174836 ISSN: 0300-5127

1. Novelty (PCT Article 33(2))

None of the prior art documents D1-D4 discloses a method of producing fats/oils/fatty acids of the formula of claim 1 using the combination of desaturases and elongases disclosed in claim 1. Claims 1 to 11 are therefore novel.

2. Inventive step (PCT Article 33(3))

None of the embodiments in the description, in which elongase and/or desaturase enzymes are introduced into the organism, discloses the specific combination of desaturases and elongases specified in claim 1. In example 8, ELO3 is expressed in yeast with either a delta-4-desaturase from *E. gracilis* or a delta-5-desaturase from *P. tricornutum* and the delta-4-desaturase from *E. gracilis*.

Thus a technical effect of the specific claimed combination of enzymes cannot be defined for claim 1. D2 describes the reconstitution of the synthesis of C20 PUFAs by means of transfection of genes of a delta-5,6 elongase from *C. elegans* with a delta-5- and a delta-6-desaturase in yeast. Claims 1 to 11 are therefore not inventive in relation to D2 (the requirements of PCT Article 33(3) are not met).

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/EP2004/007957

Supplemental Box Relating to Sequence Listing

Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
- a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing
 - ☒ contained in the international application as filed
 - ☒ filed together with the international application in computer readable form
 - ☐ furnished subsequently to this Authority for the purposes of search and/or examination
 - ☐ received by this Authority as an amendment* on _____
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

The sequence listing in the description, pages 141-354 as originally filed

* If item 4 in Box No. I applies, the listing and/or table(s) related thereto, which form part of the basis of the report, may be marked "superseded."

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box III

Since claims 12 to 34 were not the subject of international search, these claims will also not be included in the international examination (PCT Rule 66.1(e)).

Box IV

The different inventions/groups of inventions are:

1. **claims 1-11:**
 method of producing fats/oils/lipids in transgenic organisms
2. **claims 12, 13:**
 oils, lipids and fatty acids
3. **claim 14:**
 method of producing oils, lipids, fatty acids
4. **claim 15:**
 the use of oils, lipids, fatty acids
5. **claims 16-18 all in full, 25-34 all in part**
 isolated nucleic acid with delta-5-elongase activity
6. **claim 19 in full, claims 25-34 all in part**
 isolated nucleic acid delta-6-elongase activity

Supplemental Box

7. **claim 20 in full, claims 25-34 all in part**
isolated nucleic acid with omega-3-desaturase activity
8. **claim 21 in full, claims 25-34 all in part**
isolated nucleic acid with delta-6-desaturase activity
9. **claim 22 in full, claims 25-34 all in part**
isolated nucleic acid with delta-5-desaturase activity
10. **claim 23 in full, claims 25-34 all in part**
isolated nucleic acid with delta-4-desaturase activity
11. **claim 24 in full, claims 25-34 all in part**
isolated nucleic acid with delta-12-desaturase activity

These inventions/groups of inventions are not so linked as to form a single general inventive concept for the following reasons (PCT Rule 13.1):

The present application fails to meet the requirement of unity of inventive as defined by PCT Rule 13.1 and 13.2:

In order for a number of groups of inventions to have unity they must share at least one common technical feature. This common technical feature must make a contribution to the teaching of the prior art, i.e. it must be novel and inventive.

Supplemental Box

In the present case, however, the common technical features of method claim 1 and substance claims 16 to 24, which are directed to isolated nucleic acid, can only be defined as the respective enzymatic activities (delta-5-elongase, delta-6-elongase, omega-3-desaturase, delta-6-desaturase, delta-5-desaturase, delta-4-desaturase, delta-12-desaturase). These individual enzymatic activities are, however, adequately known from the prior art (for example, Drexler et al., figure 6). The common technical feature of invention group 1 and invention groups 2 to 4 is "oils, lipids or fatty acids".

However, such products are also variously disclosed in the prior art.

The applicant is therefore invited to pay additional search fees.

In the case that these fees are not paid, the search report will be limited to the first invention (PCT Article 17(3)(a), PCT Rule 13(1), PCT Rule 40).

Each of the 11 inventions has its own prior art that must be found separately. In order for this to be done, separate searches need to be carried out. Considerable extra effort would be required to search all of the aforementioned inventions. Moreover, it should be noted that there is always the possibility that overlapping sets of documents may result from independent searches. However, since it is only in hindsight, after the extra

Supplemental Box

effort has been put into the search, that this overlapping may become apparent, it cannot be argued that no extra effort is necessary for the search.

The application relates to a number of inventions or groups of inventions within the meaning of PCT Rule 13.1. The application has been divided into groups as listed above.

In the case that the applicant pays additional fees for one (or more) group(s) of inventions which has (have) not yet been searched, the additional search(es) could uncover additional prior art that could demonstrate further lack of unity of invention '*a posteriori*' within one (or more) of the groups that has (have) not yet been searched. In this case, only the first invention within each group of inventions for which a lack of unity of invention has been determined will be the subject of a search. This time the applicant will not be invited to pay additional fees, the reason being that, pursuant to PCT Article 17(3), the ISA is to establish the international search report on those parts of the international application which relate to the invention first mentioned in the claims ("main claim") and on those parts which relate to inventions in respect of which the additional fees have been paid. Neither the PCT nor the PCT Guidelines provide a legal basis for further invitations to pay additional search fees (W17/00, point 11 and W1/97, points 11-16).